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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,212	02/06/2002	Neal E. Fearnot	3433-338	8926
7590 Kenneth A. Gandy Woodard, Emhardt, Naughton, Moriarty & McNett Bank One Center/Tower 111 Monument Circle, Suite 3700 Indianapolis, IN 46204-5137			EXAMINER MILLER, CHERYL L.	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 11/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/068,212

Applicant(s)

FEARNOT ET AL.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 15, 18-30, 36-38 and 46-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/10/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's incorporation of previously indicated allowable subject matter is acknowledged by the examiner. An updated search was completed and further consideration was given to the claims. New rejections have been made thus this action is Non-Final.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25, 30, 53, and 57-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites the limitation "the extension" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is unclear whether applicant is referring to the first extension or the plurality of extensions.

Claim 30 line 4 recites, "the tube and having a plurality of extensions". This statement is unclear. It seems applicant may have intended to delete the "and". Claims 57-59 depend upon 30 and inherit all problems with the claim.

Claim 53 recites the limitation "the submucosal tissue" in line 1. There is insufficient antecedent basis for this limitation in the claim. It appears the dependency for this claim may be incorrect and may have been intended to depend from claim 52.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18-20, 22-24, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Myers et al. (US 5,910,168). Myers discloses a medical device (see fig.8) comprising a tube (10) having a lumen (seen in fig), an extension (one direction of fiber 15 windings) and an aperture (pocket formed between other fiber winding 15 and base 11), the first extension (one of fibers 15) having a portion received through the aperture (woven or braided such that it is placed through the aperture) so as to overlie an underlying layer of material (11), wherein the extension portion (part of fiber 15) is bonded to the underlying layer (11; col.10, lines 56-64), wherein the tube (10) comprises collagen (tube 10 may include a collagen coating; col.7, lines 4-8), and wherein the tube (10) has a plurality of extensions (different fibers 15) and apertures (openings located between transverse fibers 15 and base 11). Second and intermediate layers may be considered the disclosed coatings or drugs.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 49-53 and 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. (US 5,910,168). Myers discloses a medial device substantially as claimed. Myers discloses a tube comprising collagen and PTFE, however has not disclosed the use of submucosa. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use submucosa as the type of collagen or to use submucosa as an alternative to PTFE, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice (submucosa being a known material used in the vascular art area due to its biocompatibility and bioremodelability). *In re Leshin*, 125 USPQ 416.

Claims 18-20, 22, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al. (US 6,027,779, cited in IDS). Campbell discloses a medical device (see fig.2, 3 for example) comprising a tube (10) having a lumen (seen in figs), an extension (second end of first sheet 21, seen as an overlap extension in figs.2, 3) and an aperture (pocket formed between first sheet 21 and second sheet 22, into which end edge of 21 fits into), the first extension (end of 21) having a portion received through the aperture so as to overlie an underlying layer of material (second end of first sheet 21 overlies sheet 21's other end; see fig.2, 3), wherein the extension portion (second end of 21) is bonded to the underlying layer (first end of 21; col.6, lines 49-53, 65-67), wherein the tube (10) has a plurality of extensions (second end of 21 is first extension and the first end of sheet 22 is another extension; see figs.2, 3) and apertures (openings where ends of sheets 21, 22 are inserted into). Campbell discloses the medical device

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substantially as claimed, however discloses the tube to be made of PTFE instead of collagen submucosa. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use submucosa as an alternative to PTFE, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice (submucosa being a known material used in the vascular art area due to its biocompatibility and bioremodelability). *In re Leshin*, 125 USPQ 416.

Claims 18-20, 22, 30, 49-53, and 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al. (US 6,669,719 B2, cited previously). Wallace discloses a medical device (see fig.56) comprising a tube (1) having a lumen (seen in fig), an extension (plug) and an aperture (174), the first extension (plug) having a portion (bottom of plug) received through the aperture so as to overlie an underlying layer of material (bottom of plug overlies under layer), wherein the extension portion (plug) is bonded to the underlying layer (plug is made of adhesive so will bond itself to under layer; col.24, lines 52-55), wherein the tube (1) has a plurality of extensions (plugs) and apertures (174). Wallace discloses the medical device substantially as claimed, however does not disclose the tube to be made of collagen submucosa. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use submucosa as an alternative to the polymer or alloy of Wallace, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice (submucosa being a known material used in the vascular art area due to its biocompatibility and bioremodelability). *In re Leshin*, 125 USPQ 416.

Allowable Subject Matter

Claims 14, 15, 26-29, 36-38, 46-48, 54-56, 60, and 61 are allowed.

Claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 25 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/



BRUCE SNOW
PRIMARY EXAMINER